# First Annual Report of the Medical Devices Annex to the U.S./EU Mutual Recognition Agreement

## December 1, 1999

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# INTRODUCTION

Article 7 of the Medical Devices Annex to the U.S./EU Mutual Recognition Agreement (MRA) requires the Commission for the European Communities (CEC) and the government of the United States (U.S.) to prepare annual progress reports which describe the confidence building activities undertaken during each year of the confidence building period. This is the first progress report, and has been prepared jointly by the U.S. Food and Drug Administration (FDA), the National Institute of Science and Technology (NIST) and the CEC addressing the implementation on the Medical Devices Annex. It includes background on the MRA, a chronology of accomplishments and resource expenditures. This report covers activities from May 18, 1998, the date of signing of the MRA, to December 1, 1999.

# BACKGROUND ON THE U.S./EU MUTUAL RECOGNITION AGREEMENT: THE MEDICAL DEVICES ANNEX

On June 20, 1997, the U.S. and the CEC for the European Union (EU) concluded negotiation of the MRA, which covers a variety of product sectors including telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical good manufacturing practice (GMP) inspections, and medical devices. The aim of this agreement is to facilitate transatlantic trade while reducing costs for compliance with regulatory requirements. On May 18, 1998, the MRA was signed by representatives of the U.S. and the EU marking the start of implementation. On October 30, 1998, there was an exchange of letters between the Parties that inaugurated the confidence building period. This agreement became effective December 1, 1998. The Medical Devices Annex to the MRA became effective on December 7, 1998, the effective date of the FDA final rule. The effective date initiated a three year transition period during which time both sides will engage in confidence building activities. After the three year period, the agreement would become operational as to conformity assessment bodies (CABs) for which the confidence building activities are successfully completed.

The MRA consists of a framework agreement and individual sectoral annexes. The framework agreement covers the general aspects of the implementation of the agreement as well as requirements governing CABs, such as listing, suspension and withdrawal.

The Medical Devices Annex covers the exchange of quality systems evaluation reports for all medical devices and premarket evaluation reports for selected low to medium risk devices. A European CAB can conduct quality system inspections for all classes of devices and 510(k) evaluations for selected devices based on FDA requirements. Similarly, a U.S. CAB can conduct quality system audits for all classes of devices and type-testing evaluations for selected devices based on EU requirements. In addition, an alert system will be established during the transition period and maintained thereafter by which the Parties will notify each other when there is an immediate danger to public health. As part of that system, each Party shall notify the other Party of any confirmed problem reports, corrective actions, or recalls.

**CHRONOLOGY OF ACCOMPLISHMENTS TOWARDS THE IMPLEMENTATION OF THE MEDICAL DEVICES ANNEX TO THE U.S./EU MRA**

- April 10, 1998- FDA published a proposed rule in the FEDERAL REGISTER (FR), 63 FR 17744, explaining how the provisions of the Medical Devices Annex, specific to the endorsement of quality system and product evaluation reports, will be incorporated into the agency's medical device program.

- June 25, 1998- The chair of the EU Notified Body Group visited FDA and presented information on the EU medical device system and the role of the EU CABs under the MRA.

- June 30, 1998- The National Institute of Science and Technology (NIST) and the Food and Drug Administration (FDA) established criteria for the designation of U.S. Conformity Assessment Bodies (CABs)

- July 2, 1998- FDA published a notice in the FR, 63 FR 36247, identifying the process for designating EU and U.S. CABs under the Medical Devices Annex.

- July 2, 1998- FDA published a notice in the FR, 63 FR 36240, announcing the availability of a draft guidance document entitled, "Guidance for Staff, Industry and Third Parties, Third Party Programs under the Mutual Recognition Agreement Between the United States of America and the European Community," for prospective EU CABs. It detailed the criteria for technical competence and independence, format and content of dossiers and procedures for processing dossiers by the FDA. This document established the criteria for EU CABs, which is essentially identical to the requirements for independence and technical competence required of third parties under the FDA Modernization Act (FDAMA) Accredited Persons Program.

- July 31, 1998- NIST issued letters to 45 U.S. organizations inviting them to apply to participate as U.S. CABs.

- September 14, 1998- The U.S. Sectoral Lead for Medical Devices visited the National Standards Authority of Ireland (chair of the European Notified Bodies Group) and Ministry of Health officials presented information on FDA requirements and MRA implementation plans.

- September 21, 1998- By videoconference FDA and the EU held the first "Stakeholders Meeting" as part of the confidence building activities. The purpose of these meetings is to provide an update of the implementation of the Medical Devices Annex to stakeholders (industry, trade associations and consumer advocacy groups).

- October 2-5, 1998- The FDA Sectoral Lead for Medical Devices and the Chief Executive Officer of the United Kingdom's Medical Devices Agency gave presentations to Japanese industry and government on the MRA and the EU device system, respectively.

- October 14-16, 1998- FDA conducted training for third parties under the Accredited Persons Program and persons interested in applying to become EU CABs under the MRA. Representatives of 13 prospective EU CABs participated. The scope of the training was the review and processing of premarket evaluations [510(k) applications] of specific devices.

- October 16, 1998- FDA published a notice in the FR, 63 FR 55617, expanding the list of voluntary consensus standards, that are recognized by the agency, to over 400 for the premarket or 510(k) review of medical devices. The list was first published February 25, 1998, 63 FR 9561. These standards are eligible for use in the third party Accredited Persons Program under FDAMA and under the MRA.

- October 30, 1998- FDA established an Implementation Team specifically for the Medical Devices Annex. The team's primary mission is to establish an implementation plan. The team also monitors implementation activities cooperatively with the EU and the U.S. government. This includes identification of specific objectives, prioritizing them and assuring they are accomplished in a timely and efficient manner.

- November 2, 1998- At the request of the FDA, NIST issued letters to 45 prospective U.S. CABs informing them that an essential requirement for nomination is the capability to perform quality system audits with personnel within their organization.

- November 6, 1998- FDA published a final rule in the FR, 63 FR 60122, explaining how the provisions of the Medical Devices Annex specific for the endorsement of quality system and product evaluation reports would be incorporated into the agency’s medical device program. In addition, the effective date of this notice, December 7, 1998, marked the beginning of FDA’s participation in transitional confidence building activities.

- November 6, 1998- FDA published a notice in the FR, 63 FR 60165, announcing a memorandum of understanding (MOU) between the FDA and the United States Trade Representative (USTR) establishing procedures for the Joint Committee provisions of the MRA.

- November 7, 1998- At the Transatlantic Business Dialogue (TABD) in Charlotte, North Carolina, U.S. and European industry representatives proposed an MRA Implementation Plan.

- November 13, 1998- NIST held a workshop in Gaithersburg, Maryland to solicit public views regarding the establishment of the National Voluntary Conformity Assessment Systems Evaluation Program (NVCASE) Medical Devices Program that would be utilized to formally qualify and help oversee U.S. CABs.

- November 15, 1998- NIST held a briefing for persons that had expressed interest in becoming U.S. CABs and agreed to assist FDA in the designation of these bodies. The briefing included discussions of the criteria for U.S. CABs and FDA's expectations.

- December 7, 1998- FDA provided the EU with a list of 10 designated U.S. CABs at 19 different sites to be considered for participation in confidence building activities.

- December 15, 1998- FDA and the EU held the second "Stakeholders Meeting" via videoconference.

- January 1, 1999- The FDA's Center for Devices and Radiological Health (CDRH) started to exchange post market vigilance reports with foreign counterparts as part of a pilot program initiated by Study Group 2 of the Global Harmonization Task Force (GHTF). This included National Competent Authorities (NCAs) from two EU countries (Germany and the United Kingdom). To date 21 reports have been exchanged.

- January 6, 1999- FDA published a final guidance document, "Guidance for Staff, Industry and Third Parties, Third Party Programs under the Mutual Recognition Agreement Between the United States of America and the European Community". It is available at www.fda.gov/cdrh/mra.

- February 5, 1999- FDA prepared a videotape addressing the Medical Devices Annex for FDA personnel. It was shared with the 10 designated U.S. CABs. It included explanations of the MRA, the EU regulatory system and the plans for implementation of the Medical Devices Annex.

- February 8, 1999- FDA provided the EU with proposed changes to the list of devices eligible for premarket evaluation included in Tables 1 and 2 of the Medical Devices Annex. The FDA proposed to amend the list to include a total of 97 devices, 25 Class I and 72 Class II devices. In addition, 4 devices that had been listed in Table 2 are no longer eligible due to provisions of FDAMA that exclude third parties from reviewing permanently implantable and life sustaining /supporting devices. The proposed changes would by 34 increase the number of Class II devices eligible for premarket review and eliminate 39 Class I devices currently exempt from 510(k) as a result of FDAMA.

- February 18-19, 1999- FDA met with EU officials in Rockville, Maryland following the GHTF Chairman's Advisory Meeting to discuss the designation of EU CABs and development of an MRA implementation plan.

- March 1, 1999- FDA revised standard operating procedures for "The Handling of Postmarket Vigilance Reports within CDRH/FDA" to assure that there will be an exchange of significant postmarket adverse event information under the Medical Devices Annex.

- March 19, 1999- FDA and the EU held the third "Stakeholders Meeting" via videoconference.

- March 19, 1999- FDA prepared an MRA background document that is issued to all newly registered medical device firms.

- April 9, 1999- The FDA Medical Device Sectoral Lead met with European Commission officials. Later, both met with European industry on the MRA.

- April 12-14, 1999- NIST and FDA coordinated EU-sponsored training at the NIST campus in Gaithersburg, Maryland for the 10 designated U.S. CABs and FDA regulatory personnel. The scope of the training covered ISO 9001/13485 and the General Directive on Devices 1993.

- April 15, 1999- NIST held a follow-up workshop in Gaithersburg, Maryland to solicit public comments regarding the establishment of the NVCASE Medical Devices Program that would be utilized to formally qualify U.S. CABs.

- June 5, 1999- FDA established an Internet web site (www.fda.gov/cdrh/mra) for the Medical Devices Annex to the MRA.

- June 11, 1999- FDA held a audioconference with the MRA Joint Committee (JC) to discuss the amendment to Tables 1 and 2 to the Medical Devices Annex. It was agreed upon to proceed with formalization of the list.

- June 21-25, 1999- FDA coordinated training for the 15 designated EU CABs in London, conducted by AAMI, on the Quality System Regulation.

- June 27, 1999- FDA and the EU held the fourth "Stakeholders Meeting" prior to the seventh GHTF Meeting in Bethesda, Maryland.

- June 28-July 2, 1999- FDA hosted the seventh GHTF Meeting at the National Institute of Health campus in Bethesda, Maryland.

- July 9, 1999- FDA issued a letter to the EU Designating Authorities requesting EU CAB dossiers.

- July 19, 1999- FDA forwarded to the Directorate General (DG) III, now the Enterprise DG of the CEC, a draft letter to be issued by the Director, CDRH to all EU medical device firms promoting the utilization of EU CABs for marketing access to the U.S.

- July 26-30, 1999- FDA convened a meeting of field and headquarters compliance and training personnel to develop a training course for investigators and performance auditors who will be involved in joint inspections with EU CABs. Several of them stayed for part of the August 2-10, 1999 training discussed below.

- August 2-10, 1999- FDA sponsored a two-week training session for EU CABs in Rockville, Maryland. The first week addressed the Quality System Regulation, inspectional technique and report writing. Thirteen EU CABs attended. The second week included 510(k) training which was essentially the same training provided to Accredited Persons in October, 1998. Four EU CABs attended.

- August 4, 1999- FDA developed the first draft of the Confidence Building Program (Implementation Plan) for the Medical Devices Annex required by the MRA and distributed it to the Enterprise DG for comment. This program consists of, among other items, a timetable for activities, criteria for qualified CABs and the use of GHTF work products that includes 9 draft guidance documents developed by the four Study Groups.

- August 12, 1999- NIST issued a survey to the 10 designated U.S. CABs to identify additional training needs. The results of this survey was forwarded to the FDA and the Enterprise DG on September 23, 1999.

- August 31, 1999- FDA issued a letter to Mauro Petriccione of the External Affairs DG addressing the EU's concerns relayed to the office of the USTR regarding the implementation of the Medical Devices Annex. In addition to addressing the EU's concerns in detail, FDA provided a copy of another draft of the Implementation Plan for review.

- September 9,1999- NIST prepared a draft checklist of qualifications for U.S. CABs based on MEDDEV 2.10/2 and forwarded it to the FDA, Enterprise DG and ANSI-RAB for comment.

- September 20-24, 1999- FDA conducted a joint quality system inspection of an EU firm with a designated EU CAB, G-MED.

- September 22-23, 1999- FDA conducted a training program for 15 FDA Investigators and Performance Auditors who will be participating in future joint training inspections for EU CABs.

- September 22-30, 1999- FDA participated in four U.S. Department of Commerce Small to Medium-Size Enterprise Seminars on the MRA. This included representatives from the FDA's Center for Devices and Radiological Health, the Enterprise DG and members of U.S. industry, actively trading with the EU. The purpose of the conferences was to promote trade with the EU through the use of the MRA.

- October 4-8, 1999- FDA conducted a joint quality system inspection of an EU firm with a designated EU CAB, Danish Medical Devices Certification-DGM.

- October 5, 1999- NIST published a notice in the FR, 64 FR 54000, for the establishment of NVCASE programs for Accreditors. Product Certifiers were invited to apply to NIST to be Recognized Accreditors that will assess the capabilities of U.S. CABs against EU requirements.

- October 11-12, 1999- FDA met with the External Affairs DG, the Enterprise DG and the Expert Working Group in Brussels and completed the third draft of the Implementation Plan for the Medical Device's Annex.

- October 18-20, 1999- At a Study Group 2 meeting of the GHTF it was decided to continue a pilot program for the reporting of post market vigilance reports to determine if modifications to the reporting form are required and to further refine the criteria for generating a report.

- October 22, 1999- The FDA and the EU held the fifth "Stakeholders Meeting" conducted via audioconference.

- October 26, 1999- FDA and the EU held the first Joint Sectoral Committee (JSC) meeting to discuss implementation of the Medical Devices Annex, via videoconference between Brussels and Rockville, Maryland.

- November 8-11, 1999- FDA conducted a joint quality system inspection of a EU firm with a designated EU CAB, SGS Yarsley.

- November 9, 1999- NIST issued a letter to 10 U.S. CABs requesting they complete a checklist based on MEDDEV 2.10/2 and provide supporting documentation required for evaluation.

- November 22-26, 1999- FDA conducted a joint quality system inspection of an EU firm with a designated EU CAB, Danish Medical Devices Certification-DGM.

- November 29-December 2, 1999- FDA conducted a joint quality system inspection of an EU firm with a designated EU CAB, Danish Medical Devices Certification-DGM.